THE CONTROVERSY OVER INFANT FORMULA

By Stephen Solomon
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When the Jamaican woman brought her two babies to Alan Jackson's clinic at the University of the West Indies in Kingston, the pediatrician was shocked by their condition. Her 4-month-old son weighed only five pounds - two less than at birth - and her daughter was in even worse shape. At 18 months, she weighed only 12 pounds, and soon lost four more.

When Dr. Jackson questioned the woman, who had 10 other children, he discovered that she had never breast-fed her two youngest. Their diets since birth had been infant formula. Because the family income averaged only $7 a week, the mother had to heavily dilute the expensive formula to make it last longer. "For the 4-month-old baby," Dr. Jackson later told Senator Edward M. Kennedy's Subcommittee on Health and Scientific Research, "one tin of feed should have lasted for something just under three days. She said that one tin of feed lasted two weeks to feed both of the children."

There is no third-world poverty in Cooperstown, N.Y. The big homes and manicured lawns give the aura of a town happily stalled in the security of the 1950's.

But Allan Cunningham, who had been a pediatrician for a tribe of Sioux Indians before moving to Cooperstown, became aware of something odd about his new patients at Mary Imogene Bassett Hospital: Nearly all of the sick infants he treated were formula-fed.

Dr. Cunningham's subsequent investigation, published as two studies in The Journal of Pediatrics showed that illness occurred twice as often among babies who were not breast-fed; in the first two months of life, the difference was 16-fold.

Dana Raphael was one of the first scientists to hold the formula companies responsible for high infant mortality, but then she decided it wasn't quite that simple. An anthropologist who heads the Human Lactation Center Ltd., in Westport, Conn., Mrs. Raphael changed her mind after a study team she led spent two years observing how women in 11 different cultures around the world feed their babies.

What the team found was that many poor and undernourished thirdworld women are physically unable to breast-feed and that others are too preoccupied with the basics of survival to find the time to do so. Though she still strongly favors breast-feeding when possible, Mrs. Raphael now believes that the general unavailability of food is responsible for high infant mortality. "Formula is gold for the mothers who can afford it," she says. "If every 3-month-old baby could have a sufficient amount of formula, they'd all live. But the price is prohibitive. They're lucky if they can afford a cup of buffalo milk every day."

The controversy and confusion over opinions such as these reached the scale of global conflict earlier this year when the World Health Organization (W.H.O.) voted 118 to 1 to adopt a nonbinding code restricting the promotion of infant-formula products.

The United States's lone dissenting vote was explained, in part, by Elliott Abrams, Assistant Secretary of State for International Organization Affairs (since nominated to be the Assistant Secretary of State for Human Rights). "Despite our governmental interest in encouragement of breast-feeding," he said the W.H.O. recommendations for a complete ban on advertising to the general public of infant formula and the proposed restrictions on the flow of information between manufacturers and consumers "run counter to our constitutional guarantees of free speech and freedom of information."

In protest against this stand, two high-ranking health officials at the United States Agency for International Development (A.I.D.) resigned their positions and joined a chorus of critics at home and abroad. Lois Salisbury, for example, a lawyer with Public Advocates, a San Francisco firm that represents 14 national organizations, rejected the Reagan Administration's contention that marketing standards were not needed in the United States. "Studies have shown," she said, "that there is an epidemic of formula misuse among low-income families in cities like Houston and Los Angeles."

At the center of the increasingly bitter conflict are babies, millions of babies with the shriveled limbs and the distended bellies that signal kwashiorkor, the Ghanian term for malnutrition that has become part of the medical literature. According to Unicef, about 11 million infants in developing countries - more than the combined populations of New York and Los Angeles - die each year before reaching their first birthday. Most of them succumb to malnutrition or diarrheal diseases. Although estimates vary widely, Dr. Stephen Joseph, one of the A.I.D. officials who quit last May, blames reliance on infant formula for about a million of these deaths.

The formula itself is a nutritious product, and it can be an acceptable alternative to breast milk under certain conditions: when the mother can afford to buy sufficient quantities; when she has access to refrigeration, clean water and adequate sanitation, and when she can understand the directions well enough to mix the formula properly. And, as nutritionists point out, formula can save lives. Dr. Joseph remembers a cholera epidemic in Chad in 1972, when "a lot of mothers died." Fortunately, he says, "we had formula available through international agencies and we saved a number of kids."

He and many other physicians argue, however, that most third-world women cannot use formula safely and that, as a result, their babies become seriously ill and malnourished. They also charge that aggressive marketing of formula has contributed to a vast shift away from breast milk, the safest and most nutritious food for infants.

The formula companies deny that their marketing has influenced the choice of feeding methods, and they contend that misuse of their products is rare. For them, a rich global market is at stake. Formula sales in this country reached $550 million last year at the wholesale level, divided principally among Abbott Laboratories (50 to 55 percent), the Bristol-Myers Company (40 percent), and American Home Products Corporation (8 percent). In the world market, estimated to be as great as $2 billion wholesale, Swiss-based Nestle commands a 50 percent share, while the American companies and dozens of other competitors divide the rest.

Leah Margulies, a founder of Infact (Infant Formula Action Coalition), now associated with the Interfaith Center on Corporate Responsibility of the National Council of Churches, says that many antiforumula advocates are "in favor of a choice that's real; we want mothers and families to make a decision that's not based on the marketing strategy of a high-profit industry." (Among the alternatives, Infact supports suggestions by nutritionists who recommend the mixing at home of powdered milk with sugar and oil, or yogurt.)

The controversy over formula did not boil over until the publication in 1974 of a journalistic expose, "The Baby Killer," by War on Want, a London organization. The booklet, which was widely translated and distributed, brought scores of groups, many of them church-related, into the fray. While some of them launched shareholder suits and resolutions against the American manufacturers, others began a nationwide boycott of Nestle products. The nerve center of the protest became the Interfaith Center on Corporate Responsibility. Commenting on the boycott, Rafael D. Pagan Jr., president of the Nestle Coordination Center for Nutrition in Washington, says: "Nestle, of course, is a Swiss company and does not manufacture, distribute or sell infant formula in the United States, and thus there has never been any direct impact on the company through that product."

The words that each side uses against the other are not the kind usually heard among the pews on Sunday mornings. So vituperative is the rhetoric that it is easy to imagine both sides settling the issue in a back alley after dark. It is a battle in which politics and money, not science, have come to dominate.

And yet it is the scientists who must ponder such difficult questions as: How long can a malnourished mother adequately suckle her baby? If formula is denied to mothers, will they put watery gruel or weak tea into the feeding bottles instead? Can mothers combine local foods in a nutritious mixture, eliminating the need for expensive formulas, as some international organizations and a few third-world countries have suggested might be an acceptable alternative?

Mother's milk is the world's original and best fast food, a complex recipe containing more than a hundred nutrients, many of which are different chemically from those found in formula products. In most healthy women, these nutrients are enough to sustain a baby's growth for the first four to six months of life.

Mother's milk is also a potent armament against infection. Like a soldier stripped of weapons, a baby at birth lacks many of the biological agents that fight bacteria. While its own immune system matures, an infant acquires antibodies from its mother's milk that are effective against the intestinal infections that are the leading killers of infants in developing countries. "The immune system in human milk has evolved over millions of years specifically to protect infants, and it's uniquely different from milks used as substitutes," says Dr. Armond S. Goldman, a professor of pediatrics and of human biological chemistry and genetics at the University of Texas's medical branch in Galveston.

Despite its advantages, human milk has always competed against other methods of feeding. Beginning, perhaps, with those whose mothers died in childbirth, babies have fed on the milk of cows, goats, yaks and camels, horses, reindeer and buffalo. But these milks are unlike the human variety.

Since the middle of the last century, scientists have tried to modify cow's milk to make it biologically more similar to human milk and to enhance its digestability. But actual "formulas" did not appear until close to the turn of the century. A pediatric text in 1904 offered no fewer than two and a half pages of formulas for calculating the composition of infant food. Soon after, early versions of modern formula products became available without a prescription.

The infant formula is still biochemically different from human milk. The protein components in it can cause serious allergic reactions in some infants, such as diarrhea, vomiting, abdominal pains

and skin rashes. And it lacks some of the nutrients of human milk, such as taurine, which may be involved in the early development of the brain. "For us to think that in 40 years we can duplicate what has happened in four million years of human development is very arrogant," says Dr. Gerald Gaull, a pediatrics professor at Mt. Sinai School of Medicine in New York.

The companies that make formula start either with skim milk or with whole milk from cows, and remove the fat that infants find difficu to digest. After the milk has been diluted with water to reduce the level of protein, a milk sugar called lactose is added, as well as a combination of vitamins and minerals. Finally, a blend of vegetable oils is used to restore the fat, which the babies need, in a form they can digest. The formula is marketed either already mixed or in a powdered form, to which mothers add water.

The formula market did not begin its dramatic expansion until birthrates skyrocketed after World War II. Women in Western countries flocked to the feeding bottle as a "scientific" method that also liberated them from the home. The National Fertility Survey in 1965 showed that 68 percent of mothers born between 1911 and 1915 breastfed their first baby, compared with 35 percent of mothers born in the early 1940's. Surveys by Ross Laboratories, which produces Similac, show that the incidence of breast feeding at one week of age fell from 34 percent in 1951 to 23 percent in 1971. But breast-feeding resurged to 54 percent in 1980, probably because of increasing awareness of the advantages of mother's milk and the activism of groups like La Leche League, whose insistence that nature's way is best appeals to a generation weaned on ecology.

However, a recently released study conducted by the New York City Department of Health revealed that 68 percent of the mothers who gave birth in all types of city hospitals last year planned to use infant formula; the figure rose to 82 percent in municipal hospitals, where most of the maternity patients are lower-income women. Infant formula is popular with some low-income women because they see it as "a kind of status symbol," says Judith Gordon, formerly a researcher at the city's Bureau of Maternity Services, but doctors believe that a more significant contributing factor is the need for many of these women to return to work soon after giving birth, which makes formula the simplest feeding method.
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In the third world, where the controversy over formula has been the most intense, the decline in breast-feeding has been more rapid and more recent. It started among the urban elite about 20 years ago and then spread quickly throughout the population, although, for the most part, rural villagers are much less affected. While many mothers have rejected breast-feeding entirely, the biggest changes involve an earlier termination of suckling and a more widespread practice of mixed feeding, utilizing both the breast and the bottle.

A number of powerful social and economic forces have caused the shift away from the breast in developing countries. When rural mothers move to the big cities, as they have in massive numbers in recent years, the psychological stress of urban life sometimes causes a physical inability to lactate. Additionally, many of the women must take jobs outside the home, and so cannot conveniently breast-feed their children.

Aggressive promotion of formula seems to have played a large role in the decline of breast-feeding, too, although its precise impact is difficult to measure. The companies which manufacture it argue that their promotions target only urban families who have the money to buy formula in sufficent

quantity and the facilities to prepare it hygienically. And they insist that they tailor their advertising campaigns in both developed and underdeveloped countries so that formula competes only with local foods, not with breast milk. "Breast milk from a well-nourished mother is a superior product to ours," says Harry Levine, a vice president of Bristol-Meyers. "The biggest market is cow's milk, and that's what we compete against."

The companies have not always been surgically precise with their promotional activities, however. After surveying marketing practices in four underdeveloped countries during 1976 and 1977, the W.H.O. said: "The distributors themselves reported that they were not limiting the distribution of products by either geographical or socioeconomic criteria."

Until a few years ago, when they ended the practice in response to widespread protest, Nestle and the American formula companies advertised heavily in the print and broadcast media of developing countries. In Brazil, where infant formula was the most advertised product after cigarettes and soap, the advertisements usually promised, if only subtly, that formula was the modern method of infant feeding, associated with upward mobility, and that it would produce babies with fat cheeks.

The formula companies have promoted most heavily, though, through health-care systems, both at home and abroad. As Ross Laboratories indicated in a selling manual issued to its American personnel in 1975 (and later withdrawn): "When one considers that for every 100 infants discharged from the hospital on a particular formula brand, approximately 93 infants remain on that brand, the importance of hospital selling becomes obvious." Under a contract signed in 1974 with New York City, Ross was given a guarantee that every new mother leaving a municipal hospital would be given a free one-day supply of Similac.

For a time, many companies employed "mothercraft" nurses, most of whom wore white uniforms, who visited women in maternity wards and in their homes. As they helped mothers to cope with infant-rearing problems, many of the nurses also promoted their company's formula. Dressed in traditional nurses' uniforms, they conveyed the false impression that independent health professionals - not company employees - were recommending formula feeding. The major companies finally responded to harsh criticism of these practices by eliminating first the uniforms and then the nurses who had worn them.

In many third-world hospitals, the staff routinely separates the mother and baby at birth and feeds formula to the baby during its entire stay in the pediatrics ward. On discharge, the mother receives a free tin of formula and a feeding bottle. By the time the mother has finished her free tin of formula, she may be a confirmed bottlefeeder and her baby, accustomed to the easy sucking on an artificial nipple, may rebel at the more demanding task of drawing milk from a breast. Or, says Dr. Carl Taylor, chairman of the Department of International Health at Johns Hopkins University, "the mother's milk can dry up and then the baby is hooked on formula."

In Nigeria, according to the W.H.O., the average clinic may receive as many as 8,000 free cans of baby formula each year. And about five million feeding bottles - many of them gifts of the formula companies - were distributed each year during the late 1970's in India, Nigeria, Ethiopia and the Philippines.

The companies defend these practices by pointing to the same W.H.O. study, in which none of the 23,000 women, mostly in developing countries, who were asked why they had stopped breast-feeding attributed the choice to promotional practices. But as some formula critics point out, the W.H.O. researchers were not trying to measure the effects of commercial promotion, and it seems

unlikely, in any case, that questioning would have brought out the kind of subtle influence that advertising can have on decision-making.

The health consequences of the shift to bottle-feeding in the third world have been severe. Halfdan Mahler, director general of the W.H.O., says that "evidence from developing countries indicates that infants breast-fed less than six months, or not at all, have a mortality rate 5 to 10 times higher in the second six months of life than those breast-fed six months or more."

A baby who does not suckle loses the immunological protection that mother's milk provides against the bacterial assault of polluted water and primitive sanitation. In Western countries, where contamination is seldom a problem, the loss of these antibodies is not disastrous. And yet the Cooperstown, N.Y., study suggests that even infants in developed societies, when denied the immune agents in mother's milk, have higher rates of serious illness, though nutritionists caution that much more research needs to be done.

Mother's milk also provides a clean and sterile method of feeding. When babies in third-world countries feed on formula, they face myriad dangers from their bottles. Fatima Patel, a nurse who works with Peruvian Indians in the Amazon, told Senator Kennedy's committee in 1978 how villagers prepare formula in that area: "The river is used as a laundry, as a bathroom, as a toilet and for drinking water," she said. "Now, you can tell ... but to get the fuel to boil that water, she has to go into the jungle, chop a tree trunk with a machete ... and carry it on her back. No mother is going to use that hard-earned piece of wood to boil that water. ... So, the babies are drinking the contaminated water."

And if the infant does not finish its bottle of formula, the mother may save the rest, unrefrigerated, until the next feeding. "Stored at room temperature in a tropical country," says Dr. Taylor of Johns Hopkins, "you have explosive bacterial growth. So the bottle becomes a lethal instrument."

Over-dilution is another serious hazard of formula-feeding. A medical team from an Indonesian university analyzed the mothers at four health clinics in that country. Their study, published last year in The Journal of Tropical Pediatrics, revealed that only one in four women had mixed the milk reasonably close to its recommended strength, despite their above average economic and educational status and the clear directions on the cans. The researchers also found "gross contamination" of the milk by fecal organisms, through the water supply, and concluded that babies fed with a bottle should be classified "high risk." In other cases, mothers who cannot sustain regular formula purchases start using cheaper mixtures such as rice water and sugared tea.

The earliest medical studies that demonstrated the benefits of breast-feeding were conducted in the United States and Western Europe more than 75 years ago, when sanitation was poorer and infant mortality higher. These studies suggest that the risks of bottle feeding in the third world are similar to those faced by Western babies a century ago.

Contemporary reports are nearly unanimous in finding major benefits from breast-feeding. A research team at the Sao Paulo School of Medicine, for instance, studied a low-income population in that Brazilian city for two years. Its findings, published in 1980, indicated that 9 percent of the infants who were breast-fed up to the age of six months were suffering from malnutrition, compared with 32 percent of those who had received only artificial feeding.

Some of the best evidence comes from hospitals that have radically changed their policy on infant feeding. In Baguio City, in the northern Philippines, doctors had routinely separated mothers and

babies at birth and fed the babies with formula. In 1975, however, the hospital began returning each infant to its mother within an hour of birth, and mothers began breast-feeding on demand. The results were dramatic. As the incidence of breast-feeding soared, the rate of morbidity (illness) and mortality dropped dramatically.

A similar program worked just as successfully at a hospital in Puriscal, a rural region of Costa Rica. Four years after babies began suckling at their mother's side, the rate of diarrheal disease had dropped by 91 percent, meningitis by 92 percent, and lower-respiratory infection by 43 percent. The mortality rate for acute infection declined by 81 percent.

Most studies coming out of underdeveloped countries, however, have flaws in their methodology. Some compare breast-feeding with bottle feeding without specifying what is in the bottle; others rely on the mother to recall what she was feeding her infant at various times during the infant's first year. But a study conforming absolutely to the classic scientific method may not even be possible. Mothers themselves choose their method of feeding, and their choice seems to reflect some inherent differences that can bias the results. In large third-world cities, mothers who choose breast-feeding, for example, are often better-educated and have greater financial means, which may affect infant-care practices. Another difficult problem is that breast-fed babies tend to be weaned at some point to the bottle, and the reason for this change in individual cases - illness of the infant, for example - may prejudice the study.

Does this mean that the studies are meaningless, that they will not support the making of public-policy decisions about the promotion of formula? With virtually every study from underdeveloped countries pointing in the same direction, most nutritionists conclude that bottle-feeding with formula or any other food places most poor third world babies at a great risk of illness or death.

Dr. Nevin Scrimshaw, director of the M.I.T.-Harvard International Food and Nutrition Program, puts it bluntly: "The studies are conclusive. Failure to breast-feed in rural developing communities is tantamount to a death sentence." A leading figure in international nutrition for several decades, Dr. Scrimshaw was director of the Institute of Nutrition of Central America and Panama for 12 years. He is a consultant to a new M.I.T.- Harvard project to develop supplementary foods that third-world mothers can prepare in the home from local inexpensive grains and vegetables. "Breast is best," he says, "but what comes next? The problem of infant nutrition won't be solved by emphasizing breastfeeding alone. Breast-fed children in developing countries begin to falter at four months because the milk is not sufficient. The second aspect of insuring the health of children is attention to the weaning period."

The problem of what to feed infants during the weaning period is the most difficult of all. Without human milk, a baby's prognosis is often grim. Its new menu may deliver the double whammy of bacteria and low food value, starting it on a quick slide to malnutrition.

Many babies never breast-feed at all, or are weaned in the first month or two, and for them there are few options. Some type of milk product is a necessity for the youngest infants, who are unable to digest solid food. Formula is the closest alternative to human milk, and the companies that make it, of course, strongly recommend it. "When there is no breast milk, the chances of survival are small if the baby is not formula-fed," says E. Steven Bauer, vice president of Wyeth International, a subsidiary of American Home Products that makes SMA and its international equivalent, S-26.

Nutritionists agree that formula has a role in feeding the youngest infants in developing countries, but cost is the key, and only mothers who can afford to buy enough to prepare it at the proper

strength should use it, they say. The W.H.O. code on marketing recognizes this danger by permitting the distribution of formula to babies using breast-milk substitutes - but only if the distribution is free or at low cost. Since the formula companies are not charitable institutions, the likelihood of sufficient quantities being distributed under such circumstances cannot be great.

It is because so few people in developing countries can afford to buy sufficient amounts of formula - a day's feeding could cost up to one-half the average daily wage, as compared to about a dollar a day in the United States - that the United Nations subcommittee on nutrition has put it far down on its list of recommended foods. The subcommittee urges mothers to find a wet-nurse - in some cultures a relative serves this function, in others, nonrelatives will do so for an amount less than the cost of infant formula. If this is not possible, the subcommittee suggests the use of animal milk or processed animal milk, such as evaporated or powdered skim milk, or even yogurt. It also recommends the use of a cup and spoon, because they are easier to clean than a nipple and a narrow-necked bottle.

Babies who feed on breast milk, as nutritionists recommend, still need solid weaning foods added to their diet in the first year. In industrialized countries, babies can subsist on breast milk exclusively for up to six months before they need a supplemental food. But the situation is much different in the third world, where malnourished mother may not be able to produce enough milk for a baby older than four months.

Roger Whitehead, a nutritionist at Cambridge University, who lived for a time in the small Gambian village of Keneba, found that lactating mothers there could provide good nutrition for their infants for only about the first three months. After that, the babies' weight gains began to fall behind international standards until, by one year, their average weight was only 75 percent of the standard.

In this critical period, when the mother's milk can no longer meet all the baby's needs, most nutritionists agree that for the vast majority of third-world women, a combination of breast-feeding and local foods works best.

Chosen wisely, local foods can make a nutritious supplement. Most "multimixes," as they are called, are recipes for cereal-legume blends. In many nations, multimixes are packaged and sold in stores. One of the first mixes was Incaparina, which Quaker Oats and other companies marketed in Central and South America in the early 1960's. Though some have been successful, especially those heavily subsidized by local governments, most commercial mixes have been too expensive for the poor, who need them most, and have been taken off the market.

Dr. Gretchen Berggren, an assistant professor of population sciences at the Harvard School of Public Health, coordinated a combined M.I.T.-Harvard health program in Haiti, where about two thirds of all the children suffer from malnutrition. At Government nutrition centers, Haitian women learned how to prepare and cook mixtures made by combining beans with rice, corn or sorghum, all local foods. Nutrition educators and doctors closely monitored the children receiving these foods. In one district serving 100,000 people, hospital admissions for severe malnutrition fell more than 50 percent from 1968 to 1975, and deaths caused by malnutrition in children under the age of 4 dropped by 83 percent.

Nepal has been another target for nutrition programs. In 1971, a team of international health workers began distributing supplies of powdered milk and corn-soy-milk mixtures to mothers of undernourished children in one area of the country, but because many mothers prepared it under unsanitary conditions, this food caused diarrhea. Medical workers then discovered that even the

poorest homes had an ample supply of grains. The nutritionists concocted a flour from local corn, wheat and soybean supplies, and then taught Nepalese women how to prepare it. Malnourished children were usually well on the way to recovery within five weeks of starting on the mixture.

In a recent effort to help infants in urban slums and poor rural areas of Thailand, a team of physicians from Bangkok prepared seven weaning supplements from locally available foods. Rice, the local staple, was the major ingredient in each mixture, to which physicians added combinations of vegetable oil, soybeans, mung beans, groundnuts, sesame and fishmeal. They reported that these gruellike mixes were nutritious, easy to prepare and acceptable to children's tastebuds and digestive tracts.

Only large government subsidies can bring packaged mixes within reach of the world's poor, but much smaller sums could help people to prepare the same mixtures at home. The M.I.T.-Harvard project, one of the first steps in this direction, gets only $200,000 a year out of America's billion-dollar-plus food-aid package.

The same companies criticized for marketing formulas may, ironically, hold one of the keys to improving the health of infants in the third world. They possess the expertise and the financial resources to help develop weaning mixtures that women can prepare with indigenous foods in their homes. And they already have the sales personnel, distribution channels and marketing apparatus to promote packaged mixtures of the same foods.

Help from this quarter, however, may be a long time coming. Still engaged in a bitter struggle over the marketing of formulas, the companies are worried that the boycott of Nestle products may spread to their own. Others are reluctant to apply their expertise to different areas. "We're a pharmaceutical company," says Carol Emerling, secretary of American Home Products. "We can make a better contribution to infant health by doing something we do well."

Nevertheless, with the trend of scientific thinking favoring mixes of local foods, infants would profit from an alliance of the formula companies and their critics.

Stephen Solomon is a contributing editor to Science Digest.

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